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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,356	05/09/2001	Martin A. Cheever	014058-009811US	1297

20350 7590 09/09/2002

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 09/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,356

Applicant(s)

CHEEVER ET AL.

Examiner

Misook Yu

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 93-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 93-112 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 93 in part, 97-102 in part, drawn to a chimeric protein by fusing SEQ ID NO:3 to SEQ ID NO:4, pharmaceutical composition comprising the chimeric protein, classified in class 530, subclass 350 and class 424, subclass 184.1.
- II. Claims 93 in part, 94, 97-102 in part, 103 in part, 104, 107-112 in part, drawn to a chimeric protein by fusing SEQ ID NO:3 to SEQ ID NO:2, pharmaceutical composition comprising the chimeric protein, classified in class 530, subclass 350 and class 424, subclass 184.1.
- III. Claims 93 in part, 95, 97-102 in part, drawn to a chimeric protein by fusing SEQ ID NO:8 to SEQ ID NO:4, pharmaceutical composition comprising the chimeric protein, classified in class 530, subclass 350 and class 424, subclass 184.1.
- IV. Claims 93 in part, 96, 97-102 in part, 103 in part, 106, 107-112 in part, drawn to a chimeric protein by fusing SEQ ID NO:8 to SEQ ID NO:2, pharmaceutical composition comprising the chimeric protein, classified in class 530, subclass 350, class 424, subclass 184.1.
- V. Claims 103 in part, 107-112 in part, drawn to a chimeric protein by fusing SEQ ID NO:3 to SEQ ID NO:5, pharmaceutical composition comprising the chimeric protein, classified in class 530, subclass 350 and others.
- VI. Claims 103 in part, 105, 107-112 in part, drawn to a chimeric protein by fusing SEQ ID NO:8 to SEQ ID NO:5, pharmaceutical composition comprising the chimeric protein, classified in class 530, subclass 350 and others.

The inventions are distinct, each from the other because of the following reasons:

Inventions groups I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions groups are different products made by fusing extracellular domains of Her-2 from human and other species to phosphorylation domains of Her-2 from human and other species. The different chimeric proteins have different structural and molecular characteristics as evidenced by the different SEQ ID Nos and the biological activities of each of the construct is difficult to predict because they are proteins, for example changing a single amino acid of a protein changes the biochemical and biological activity of the protein. Wang, J. et al. 2000 J. Biol. Chem. 275 (1): 507-513 provide evidence that even a single amino acid change converts a potent nuclease into a protein without any nuclease activity (see Fig. 3, 4, and 5) and the single amino acid change also converts the in vivo function of the protein in an unpredictable way (see Table 1).

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. The search required for each of the above inventions is not coextensive with regard to the literature and the sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, restriction for examination purposes is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention.

Groups I-VI contain claims generic to a plurality of disclosed patentably distinct species. The different adjuvants listed in claims 102 or 112 are patentably distinct because they are structurally different and biological effect of each of the adjuvant is different. If group any of the groups I-IV is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

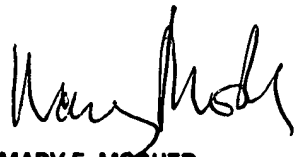
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Misook Yu, Ph.D.
August 29, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600